

PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Fischetti et al.

Serial No. 09/844,435

Group: 1618

Filed: April 30, 2001

Examiner: Raj Bawa

The Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

PROPRIETARY INFORMATION DISCLOSURE STATEMENT

Sir:

The attached is a proprietary list of patents and patent applications filed by the inventors or the owners of the present invention. Most of the patent applications will not issue before the issue date of the above listed serial number. It is therefore requested that those patent applications on the attached list not issued prior to the issuance of the above listed patent be redacted.

Applicant provides the following summaries of the enclosed prior art, along with a Form PTO-1449, all of which are enclosed.

The statement is submitted under the provisions of 37 CFR 1.56 and 1.97(b)(1).

Respectfully submitted,

01/16/2002 MGEBREM1 00000097 09844435

01 FC:126

180.00 OP

Attorney for Applicant Reg. No. 34,830

Jonathan E. Grant Grant Patent Services 2120 L Street, N.W. Suite 210 Washington, D.C. 20037 (301) 603-9071

Please	type a	a plus	sian	(+)	inside	this box	-

PTO/SB/08A (
Approved for use through 10/31/2002. OMB 0651U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMME

er the Paperwork Reduction Act of 1995, n	17	- ADV	U.S. Patent an	d Trademark Office	: U.S. DEPARTI	MENT OF COM
ler the Paperwork Reduction Act of 1995, n	o persons ane pert	rived to respond	to a collection of	information unless	it contains a vali	d OMB control

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	ı	of	5

Col	mplete if Known	ENT
pplication Number		33
iling Date		76
irst Named Inventor		8
Froup Art Unit	16185	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
xaminer Name	BAWA, R.	90
ttorney Docket Number		0

			U.S. PATENT DOCL	JMENTS	
Examiner Initials*	Cite No.1	U.S. Patent Document Kind Code ² (If known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		6,264,945	Fischetti et al.	07-24-2001	
		6,254,866	Fischetti et al	07-03-2001	
		6,248,324	Fischetti et al	06-19-2001	
		6,238,661	Fischetti et al	05-29-2001	
		6,056,955	Fischetti et al	05-02-2000	
		6,056,954	Fischetti et al	05-02-2000	
		6,017,528	Fischetti et al	01-25-2000	
		5,997,862	Fischetti et al	12-07-1999	
		5,985,271	Fischetti et al	 11-06-1999	
		5,688,501	— Merril et al. —	11-18-1997	
		4,957,686	—— Norris ———		
		5,604,109	Fischetti et al.	02-18-1997	
		5,882,631	— Suga et al. —		
		5,741,487	Asai et al.	 04-21-1998 	
		— 6,113,887 —	— Mori et al.	09-05-2000	
		- 4,122,158	—— Schmitt ——	 10-24-1978 	
		-3,983,209	Schmitt		
		- 6,113,887	—— Mori et al. ——		
		4,885,163	Shaar et al.	12-05-,1989	

				FORI	EIGN PATENT DOCUMENT	rs		
Examiner Initials*	Cite No.1	Office ³	Foreign Patent Do	Cument Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant	T
-		Ollice.		(II KIIOWII)		MM-DD-YYYY	Figures Appear	
			_ WO 97 023 _ WO 96 073 _ EP 0 510 90 _ WO 99 048	29 A	CIBA GEIGY AG, et a UNIV. MARYLAND AGRICULTURAL & F AMBI INC	_ 03-1 FOOD RES_10-2	4-1996	
				`				

		1.1.1.1	
Examiner	Date		
Signature	 Considered		

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

lease type a plus sign (+) inside this box → Jan 1 2002 Under the Paperwork Reduction Act of 1995, no persons are required to re	U.S. Patent and Tradema espond to a collection of information	ed for use through 10/31/2002. (irk Office: U.S. DEPARTMENT C in unless it contains a valid OMB	DE COMMERCE	REC
Substitute for form 1449A/PTO		omplete if Known		È
	Application Number		∞	<u> </u>
INFORMATION DISCLOSURE	Filing Date	Ĭ	8 8	=
STATEMENT BY APPLICANT	First Named Inventor		20	m
	Group Art Unit	1619	99	\coprod
(use as many sheets as necessary)	Examiner Name	BAWA	5 (J

Attomey Docket Number

			U.S. PATENT DOC	JMENTS	
Examiner Cite Initials No.		Document Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	6,177,554 6,187,757 6,132,970 5,162,226 6,335,012 6,326,002 6,277,399	4	Woo et al. Clackson et al. Stemmer Beachey et al. Fischetti et al. Fischetti et al.	12-04-2001	

				FORE	IGN PATENT DOCUMEN	rs		
Examiner	Cite	F	oreign Patent Do		Name of Patentee or	Date of Publication of	Pages, Columns, Lines, Where Relevant	
Initials	No.1	Office ³	Number ⁴	Kind Code ⁵ (if known)	Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	T6
								ļ
								1
		├ ──├─						-
				- - 				T
								1—
								\vdash
 	<u></u>					 		-

Examiner	Dat	ate		
Signature		onsidered		

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Sheet

of

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box Under the Paperwork Reduction Act of 1995, no persons are required by the paper of the pa	Approv U. S. Patent and Tradem	PTO/SB, red for use through 10/31/2002. ON ark Office: U.S. De Availd ONE on	AB 0651-063 COMMERC
Substitute for form 1449B/PTO		mplete if Known	76
INFORMATION DISCLOSURE	Application Number		Ş
I INCURINATION DISCI CISTRE	Eiling Data		V =

STATEMENT BY APPLICANT

Sheet

(use as many sheets as necessary)

	THE STATE OF THE STATE OF THE	
Com	olete if Known	16
Application Number		8
Filing Date	_	<i>1</i> 2
First Named Inventor	•	ğ
Group Art Unit	1619	
Examiner Name	BAWA	
Attorney Docket Number		

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials' publisher, city and/or country where published. Reisenger, et al. (1998) "Characterization of Escherichia coli lysis using a family of chimeric E-L Genes" Fems Microbiol Letter. 164(1) p.159-167 Sheehan MM, et al. (1997) "The lytic enzyme of the Pneumococcal Phage Dp-1: a chimeric lysis of intergeneric origin." Mol. Microbiol. 25(4) p. 717-725 Young et al. (2000) "Phages will out: stragegies of host cell lysis." Trends in Microbiology. 8(4) p. 120-127 Garcia et al.(1997) "The Pneumococcal cell wall degrading enzymes: A modular design to create new lysins?" Microb. Drug Resist. 3(2): p. 199-211 Sheehan MM, et al., (1997) "The Lytic Enzyme of the Pneumococcal Phage Dp-1: a Chimeric Lysin of Intergeneric Origin" Mol. Microbiol. 25(4) p. 717-25 Garcia P, et al. (1997) "Bacteriophages of Streptococcus pneumoniae: a molecular approach" Microb. Drug Resist. 3(20) 165-76. Sheehan, MM, et al.(1996) "Analysis of the catalytic domain of the lysin of the lactococcal bacteriophage Tuc2009 by chimeric gene assembling." FEMS Microbiol.Lett. 14(1): p. 23-28. Sanz, JM, et al. (1996) "Construction of a multifunctional pneumococcal murein hydrolase by module assembly." Eur. J. Biochem. 235(3):601-5 Lopez R, et al. (1995) "Architecture and Domain Interchange of the Pneumococcal Cell Wall Lytic Enzymes" Dev. Biol. Stand. 85 p. 273-81.

	The state of the s
Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box Under the Paperwork Reduction Act of 1995, no persons are required to res	Approve	ed for use through 10/31/2002. OM	
Substitute for form 1449B/PTO	Cor	mplete if Known	三 第二(
	Application Number		7 ∞ E
INFORMATION DISCLOSURE	Filing Date		~ _
STATEMENT BY APPLICANT	First Named Inventor		2001 2001
	Group Art Unit	1619	
(use as many sheets as necessary)	Examiner Name	BAWA	8 6

Attorney Docket Number

		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	Т
Examiner nitials*	Cite No.1	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т
		Croux, et al.(1993) "Interchange of Functional Domains Switches Enzymes	T
		Specificity: Contstruction of a chimeric pneumococcal-clostridial	
		cell wall lytic enzyme." <i>Mol. Microbiology</i> . 9(5) p. 1019-25.	t
		Diaz, E. et al. (1990) "Chimeric phage-bacterial enzymes: a clue to	l
		the modular evolution of genes. <i>PNAS</i> . 87(20) p. 8125-9.	
		Diaz, E. et al.(1990) "Chimeric pneumoccal cell wall lytic enzymes reveal important physiological and evolutionary traits."	t
		J. Biol. Chem.266(9) p. 5464-71.	+
		Lopez, et al. (1997) "The pneumococcal cell wall degrading enzymes:	
		A modular design to create new lysins?" <i>Microbiological Drug Resistance</i> , 3(2) p. 199-211.	
		Loessner, et al. (1999) "Evidence for a holin-like protein gene fully embedded out of frame in the endolysin gene of <i>Staphylococcus aureus</i> Bacteriophage."	
		(1999) Journal of Bacteriology, 181(15) p. 4452-4460.	
		Witte, A et al. (1998) "Characterization of Escherichia coli lysis using a family of chimeric E-L genes." FEMS Microbiol. Lett., 164(1), p. 159-167	\dagger
		Martin, Ana C et al (1998): "Functional analysis of the two-gene lysis system of the pneumococcal phage Cp-1 in homologous and heterologous host cells." Journal of Microbiology 180(2), p. 210-217	
		Oki Masaya et al. (1997) "Functional and structural features of the holin HOL protein of the Lactobacillus plantarum phage phi-gle: Analysis in Escherichia coli system." Gene (AMSTERDAM) 197(1-2) p 137-145.	

Sheet

(use as many sheets as necessary)

of

5

Examiner	Date	
Signature	 Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box Under the Paperwork Reduction Act of 1995, no persons are RADETO res	Approved	for use through 10/31/2002	D/SB/08B (PA-PD) 2. OMB 065 14031 T OF COMMERCE 1B control stamper.	で で つ
Substitute for form 1449B/PTO		pl te if Kn wn	<u> </u>	ĺ
	Application Number		_& & >	
INFORMATION DISCLOSURE	Filing Date		1007	
STATEMENT BY APPLICANT	First Named Inventor		<u>8</u> 111	
OTATEMENT BY ATTEMATI	Group Art Unit	1619		
(use as many sheets as necessary)	Examiner Name	BAWA		
Sheet 5 of 5	Attorney Docket Number)	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Young, Ry et al. (2000) "Phages will out: strategies of host cell lysis." Trends in Microbiology, 8(3) p 120-127.	
		Nelson, et al. (2001) "Prevention and elimination of upper respiratory colonization of mice by Group A Streptococci by using a bacteriophage lytic enzyme." <i>PNAS</i> . 98 (7) p. 4107-4112	
		Garcia, et al. (1987) "Purification and biochemical characterization of the pneumococcal bacteriophage Cp-1 lysin." Journal of Virology 61(8)	
- 18. - 18.		Loessner, et al. (1996) "Modified Listeria bacteriophage lysin genes (ply) allow efficient overexpression and one-step purification of biochemically active fusion proteins." <i>Applied and Environmental Microbiology</i> . 62(8) p. 3057-3060	
		.p. 3037-3000	
			-

٢	Examiner	Date	
	Signature	Considered	
1	Cignatalo		

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

RECEIVED

JAN 1 8 2001 TECH CENTER 1600/2900

LIST OF NEW HORIZON PATENTS AND PATENT APPLICATIONS

Title	A Method for Exposing Group A Streptococci Antigens and an Improved Diagnostic Test for the Identification of Group Streptococcus.	Therapeutic treatment of Group A Streptococcal Infections	Therapeutic Treatment of Group A Streptococcal Infections	Prophylactic and Therapeutic Treatment of App of Group A Streptococcal Infections	Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Various Illnesses	Use of Bacterial Phage Associated Lysing Enzymes for Treating Various Illnesses	Parenteral Use of Bacterial Phage Associated Lysing Enzymes for the Therapeutic
Inventors	Fischetti	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis
Issue Date	02-18-97	12-7-99	01-25-00	11-16-99	05-02-00	05-29-01	07-24-01
Filing Date	09-13-94	10-31-97	02-25-99	02-25-99	09-14-99	04-18-00	01-14-00
Country	U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.
Patent/Application No.	Pat. No. 5,604,109	Pat. No. 5,997,862 App No.09/962,523	Pat. No. 6,017,528 App No. 09/257,025 (Cert. of Correction)	Pat. No. 5,985,271 No.09/257,026 (Cert. of Correction)	Pat. No. 6,506,954 App.No. 09/395,636 (Cert. of Correction)	28 28,661 29 20,497,495	2 Pat. No. 6,264,945 2 Pat. No. 09/482,992

Treatment of Bacterial Infections

Topical Treatment of Streptococcal Infections	The Use of Phage Associated Lytic Enzymes For the Rapid Detection of Bacterial	A Composition for Treatment of A Bacterial Infection of An Upper Respiratory Tract	Use of Phage Associated Lytic Enzymes For Treating Bacterial Infections of the Digestive Tract	A Composition for Treatment of a Bacterial Infection of the Digestive Tract	Compositions Incorporating Bacterial Phage Associated Lysing Enzymes For Treating Dermatological Infections	A Composition for Treatment of Vaginal Bacterial Infections	A Composition for Treatment of An Ocular Bacterial Infection	Bacterial Phage Associated Lysing
Fischetti Loomis	Trudil	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti
05-02-00			07-03-01		08-21-01			10-19-01
09-14-99	09-01-00	09-01-00	09-01-00	09-01-00	09-28-00	09-28-00	09-28-00	09-28-00
U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.
Pat. No. 6,056,955 App. No.09/395,637	App. No. 09/654,484	App. No. 09/654,483	Pat. No. 6,254,866 App. No. 09/653,690	App. No. 09/654,482	Pat. No. 6,277,399 App. No. 09/671,882	App. No. 09/671,881	App. No. 09/671,880	Pat. No. 6,248,324

Enzymes fo Treating Dermatological Infections	The Use of Bacterial Phage Associated Lytic Enzymes for Treating Dermatological Infections	A Composition for Treating Dental Caries Caused by Streptococcus Mutans	A Method for Treating Dental Caries Caused by Streptococcus Mutans	S	The Use of Bacterial Phage Associated Lysing Enzymes for Treating Bacterial Infections of the Upper Respiratory System	The Use of Bacterial Phage Associated Lytic Enzymes to Prevent Food Poisoning	The Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Various Illnesses	The Parental Use of Bacterial Phage Associated Lysing Enzymes For The Lysing Enzymes for the Therapeutic
Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	ONG CLAIM	Fischetti Loomis	Fischetti Loomis Trudil	Fischetti Loomis	Fischetti Loomis
			01-01-02	WRONG TITLE AND THE WRONG CLAIMS	12-04-01			
	09-28-00	09-28-00	09-28-00		09-28-00	11-02-00	04-28-00	01-03-01
	U.S.A.	U.S.A.	U.S.A.	RINTED THE	U.S.A.	U.S.A.	U.S.A.	U.S.A.
App. No. 09/671,879	App. No. 09/671,878	App. No. 09/671,991	Pat. No. 6,335,012 App. No. 09/671,992	NOTE: THE USPTO PRINTED THE	Pat. No. 6,326,002 App. No. 09/671,990	App. No. 09/704,148	App. No. 09/560,650	App. No. 09/752,731

S
⊑
0
:=
ွှ
ഘ
7
\blacksquare
ಡ
∵⊏
a)
ಕ
ਕ
m
,
¥
0
Ħ
7
~
ш
#
65
ĭ
—
-

The Use of Bacterial Phage Associated Lysing Enzymes for Treating Various Illnesses	The Use of Bacterial Shuffled and Chimeric Phage Associated Lytic Enzymes for the Prophylactic and Therapeutic Treatment of Colonization and Infections caused By Streptococcus Pneumoniae	The Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Colonization and Infections Caused by Streptococcus pneumoniae	Parenteral Use of Bacterial Phage Associated Lysing Enymes for the Therapeutic Treatment of Bacterial Infections	The Use of Bacterial Phage Associated Lytic Enzymes to Prevent Food Poisoning	The Use of Bacterial Phage Associated Lysing Enzymes For
Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis	Fischetti Loomis
07-13-01	09-24-01	09-24-01	07-19-01	07-13-01	04-30-01
U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.	U.S.A.
App. No. 09/932,460	Prov. No. 60/324,089	App. No. 09/960,472	App. No. 09/908,737	App. No. 09/910,940	App. No. 09/844,435

Treating Various Illnesses

The Use of Bacterial Phage Associated Lysing Proteins for the Prophylactic and Therapeutic Treatment of Various Illnesses	A Means for the Prophylactic and Therapeutic Treatment of Streptococcal Infections
Fischetti Loomis	Fischetti Loomis
A. 05-02-01	PCT 02-25-99 INDIA EPO JAPAN RUSSIAN FEDERATION POLAND BRAZIL NEW ZEALAND NORTH KOREA SINGAPORE CANADA ISRAEL AUSTRALIA CHINA
U.S.A.	PCT INDIA EPO JAPAN RUSSIAN POLAND BRAZIL NEW ZEA NORTH K SINGAPC CANADA ISRAEL
App. No. 09/846,688	PCT/US99/04063 N/A 99909595.3 2000-600679 2001126302 not yet filed P19917152-0 514260 2001-700898 200105279-4 N/A 145087 28767/99 N/A